



cGMP Manufacturing

Many CMOs claim over a hundred years of collective industry experience as a competitive advantage. We have this experience and more. Our team has spent the last 15 years working together to manufacture viral vector products from Phase I clinical trials through commercial launch. We are also the only CMO team that has successfully filed both a Biologics License Application (BLA) with the FDA and a Marketing Authorization Application (MAA) with the EMEA. We understand the technical and regulatory requirements at all stages of product development and customize client programs to ensure project success.

Process Development and cGMP Manufacturing

- Experience with adherent and suspension cell lines
- Upstream process development
- Downstream process development
- Preclinical and toxicity study material production
- Assay development
- Technology transfer
- cGMP manufacturing up to 500L
- Large scale ultra/diafiltration
- Chromatographic purification
- Cell Bank production
- Cell Bank characterization
- Virus Bank production
- Virus Bank characterization



Product Types Manufactured

- Adenoviral vectors
- AAV vectors
- Lentiviral vectors
- Other viral products

Experience. Rapid Results.

Vivante GMP Solutions
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Vivante GMP Solutions

Expertise

Vivante has more late-stage viral vector manufacturing experience than any other CMO.

Compliance

Our team will apply our extensive regulatory and compliance experience to your project. We have successfully filed a BLA and two MAAs for a viral vector product.

Service

Having had our own product development pipeline, we know how critical having the right CMO partner is. Our team cares as much about your project as you do, and it shows in the outstanding customer service we provide.

Process Development

- Fully characterized production cell lines
- Cell line and culture process optimization
- Purification development
- Pre-clinical manufacturing
- Potency assay development
- Technology transfer
- Formulation development

QC and Stability Testing

- Client assay transfer and validation
- Analytical and cell based methods
- Raw material release testing
- Product release testing
- ICH compliant stability testing

cGMP Manufacturing

- Bulk production of Phase I-III clinical trial products
- Multiple production platforms for suspension and adherent cells
- Large scale ultra/diafiltration
- Large scale chromatographic purification
- Virus bank production and characterization
- Cell bank production and characterization

QA and Regulatory Support

- Fully compliant quality systems
- Dedicated quality assurance team
- QP inspected facility
- IND and CMC preparation
- DMF on file with FDA

Aseptic Fill and Finish

- Component preparation
- Compounding/formulation suites
- Class 100 filling suite
- Liquid and lyophilized products
- Labeling

cGMP Storage & Materials Mgmt

- Secure facility
- FDA and ICH compliant storage
- 24-hour temperature monitoring
- Backup generators
- Inventory control
- Clinical trial distribution with temperature monitoring